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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES, AND **TOXIC SUBSTANCES**

MEMORANDUM

April 9, 1996

SUBJECT:

Chlorothalonil, Meeting With Registrant's Scientists re Dermal Absorption,

Dermal Risk Assessment and Dermal Toxicity

TO:

Mary Clock

Risk Characterization and Analysis Branch

Health Effects Division (7509C)

Andrew Ertman (PM) Reregistration Branch

Special Review and Reregistration Division (7508W) -4/9/96

FROM:

Robert P. Zendzian Ph.D. Senior Pharmacologist Toxicology Branch I

Health Effects Division (7509C)

On Wednesday April 3, 1996 a meeting was held on Chlorothalonil with representatives of the Registrant (ISK) to discuss the dermal risk assessment and the role of dermal absorption. Attending were Dr. William Busey of Experimental Pathologies Laboratories Inc. and Dr. Maija Mizens of Ricerca Inc. representing ISK and Drs. Mike Ioannou and Robert Zendzian and Ms Mary. Clock representing the

In the meeting it was decided to abandon the pursuit of data on the dermal absorption of chlorothalonil and perform a short term dermal toxicity study in the rat. The study will be designed to provide a dermal NOEL that can be used directly in risk assessment calculations following dermal exposure. Such a study will avoid a veriety of assumptions that must be made in applying dermal absorption data and provide a simpler and more realistic risk assessment.

The experimental design of the study was discussed and the Registrant's representatives agreed to provide a draft protocol for Agency review. Briefly, the study will be a 28-day dermal toxicity study in the male rat (the most sensitive species and sex). The study will follow the guideline for dermal toxicity studies but will focus specifically on the established toxicity of chlorothalonil. Emphasis will be on irritation at the application site and toxicity to the kidney and forestomach. It is estimated that the study can be performed to completion of report in six months.

In order to use a NOEL from this study OREB must provide dermal exposure (mg/kg/day) estimates for Chlorothalonil use patterns.

CC D. Edwards and M. Ioannou